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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,723	02/23/2006	Takao Komatsuda	3240-7498US	6602

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
05/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,723	KOMATSUDA ET AL.	
	Examiner	Art Unit	
	MEDINA A. IBRAHIM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *3,9-11,14,15,19,20,24,26,27,29,30 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-8,12,13,16-18,21-23,25,28,31,32 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/05 and 04/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-2, 4-8, 12-13, 16-18, 21-23, 25, 28, 31-32, and 37-39, in the reply filed on 02/19/08 is acknowledged. The requirement is made FINAL.

2. Claims 1-39 are pending.

3. Claims 1 (in-part), 3, 9-11, 14-15,19-20, 24, 26-27, 29-30, 33-36 are withdrawn from consideration as being directed to the non-elected invention.

4. Claims 1 (in-part), 2, 4-8, 12-13, 16-18, 21-23, 25, 28, 31-32, and 37-39 are examined.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

6. Claims 1 and 5-8 are objected to for reciting non-elected invention, drawn to FHB resistance/susceptible barley and related triticum spp and methods of producing the same. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 2 is indefinite because "the test plant" lacks antecedent basis in claim 1. Clarification is required to more clearly define the metes and bounds of the claim.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-2, 4-8, 12-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying row type in barley by using the molecular markers *MWG801, CMWG699, MWG865* or the nucleotide sequence of SEQ ID NO; 1-5, does not reasonably provide enablement for a method of identifying row type in a triticaea plant by using exemplified or non-exemplified molecular markers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of identifying row type in a barley or related *Triticeae* plant, comprising the use of at least one molecular marker shown in the linkage maps of FIGS. 1 and 2, that is linked with a gene that controls row type; said method, wherein the test plant is identified as having two-rowed or six-rowed spikes;

said method, wherein the molecular marker comprises the nucleotide sequence set forth in any of SEQ ID NOS: 1 to 5, or a partial sequence thereof; the method comprising the steps listed in claims 5-7. The claims are also drawn to a method of generating artificially altered barley or related *Triticeae* plant comprising selecting at an early stage a plant identified as two-rowed or six-rowed plant.

The specification provides guidance for the construction of row type linkage maps and identification of molecular markers using BC7F3, BC6F2 and BC7F1 barley populations produced from a cross Azumamugi/kanto Nakate Gold and F2 populations of Azumamugi/Golden Promise and Azumamugi/Hanna as shown in Table 1 (Example 1). The specification also provides guidance for the amplification of DNAs from the six-rowed and two-rowed populations by AFLP methods to produce five markers that show polymorphisms (Table 2 and Figure 2).

The specification, however, does not provide guidance for a single Triticum plant species that can be used in the claimed methods or with the exemplified or non-exemplified molecular markers as recited in the claims. The specification is silent regarding a barley related Triticeae plant that has two-rowed or six-rowed spikes, or a method of identifying said Triticeae species. The specification neither discloses molecular markers other than the AFLP markers of Figure 1 and 2 nor a partial sequence of any of SEQ ID NO: 1-5 that can be used in the claimed identification methods. In addition, the specification does not teach a method of generating artificially altered barley or related *Triticeae* plant having two rowed or six rowed spikes by simply selecting a plant identified as two-rowed or six-rowed plant at an early stage. No

guidance has been provided for the production of an artificially altered Triticum plants. It is also noted that the plants used in the claimed methods and plants produced by the method are either two-rowed or six-row barley plants. No artificially altered Triticum plant has been used or produced in the claimed methods.

The state of the prior art is that the assignment of molecular markers to particular traits is unpredictable and population-specific. The prior art teaches that it is unpredictable whether any particular PCR-derived or RFLP molecular marker developed with one population of plant species may be successfully utilized with another population comprising the same species. For example, Concibido et al (Crop Science (1997) 37:258-264) teach that when one set of RFLP markers developed from one population of soybeans produced from one set of parental genotypes were used with two other different populations of soybeans produced by two different crosses, that the same markers yielded only 36.2% or 40.3% polymorphisms, and that the other markers were not polymorphic in these populations and could not be used (see page 260, first column, line 16 to page 261, first column, line 12).

Westman et al (Theor. Appl. Genet. 96:272-281, 1998) teach that single sequence repeat (SSR)-primer based assays do not amplify across all related genotypes, and even if they do, the bands are often mistakenly misinterpreted as allelic when they are not (see page 272, first column, line 30 to page 293, first column, line 15).

Therefore, given the breadth of the claims encompassing a method that employs a Triticaceae plant population and the use of any a partial sequence of any of SEQ ID

NO: 1-5, the unpredictability in the art, the limited guidance and working examples in the specification, and nature and the state of the prior art as discussed supra, the claimed invention is not enabled throughout the broad scope. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 17-18, 21-23, 28, 31-32, and 37-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Jui et al (Theor. Appl Genet (1997) 94:549-656) and Kamatsuda et al (genome (1999) 42(2): 248-253, Applicant's IDS).

Jui et al teach two-rowed and six-rowed barley plants and grain produced by crossing barley line Leger (six-rowed) and CI9831 line (two-rowed) spikes; and the progeny plants and their parents were tested for agronomic traits such as grain yield, seed weight and plant height (see pages 550-551; Tables 1 and 2).

Kamatsuda et al teach barley plants with two-row and six-row spikes produced from a cross between a parent with two rowed spikes (KNG) and a plant with six-rowed spikes (AZ); successive backcrosses of the F1 progeny to the parent AZ produced three BC6F1 plants. The BC6F1 plants were either grown in the controlled environment or in the field, and then the kernel row type of the resultant plant and seed were recorded (see the whole document, especially, pages 249, Methods and Materials; and Results).

The claimed barley plant/seed differ from the prior art barley plant/seed only by the method they are produced.

Hence, the instantly claimed barley plant/seed are indistinguishable from the prior art barley plant/seed based on the teachings of the specification.

Alternatively, if the claimed barley plant/seed are not identical to the prior art barley plant/seed, then it appears that they differ from the prior art plant/seed due to minor morphological variation, wherein said minor morphological variation would be expected to occur upon cultivation of said plants on different soil types with different nutrient supplements and under different environmental growth conditions such as temperature, humidity, light, etc. in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to the prior art seed.

Since Applicant has not disclosed morphological and/or physiological characteristics for the claimed barley plants, other than two-row or six-row type, they are deemed to be anticipated by or obvious over the hybrid seed of the prior art.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

15. Claims 1-2, 4-8, 12-13, 16-18, 21-23, 25, 28, 31-32, and 37-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kamatsuda et al (genome (1999) 42(2): 248-253, Applicant's IDS) and Tanno et al (Theor Appl Genet (2002) 104:54-60).

16. The claims are drawn to methods of identifying row type in a barley or related *Triticeae* plant, comprising the use of at least one molecular marker shown in the linkage maps of FIGS. 1 and 2, that is linked with a gene that controls row type; the method, wherein a test plant is identified as having two-rowed or six-rowed spikes; said method, wherein the molecular marker comprises the nucleotide sequence set forth in

any of SEQ ID NOS: 1 to 5, or a partial sequence thereof; the method comprising the steps listed in claims 5-7; and barley plants and reproductive material thereof produced by said methods.

Komatsuda et al teach a method of producing barley plants with two-row and six-row spikes produced from a cross between a parent with two rowed spikes (KNG) and a plant with six-rowed spikes (AZ); successive backcrosses of the F1 progeny to the parent AZ produced three BC6F1 plants. The BC6F1 plants were either grown in the controlled environment or in the field, and then the kernel row type of the resultant plant and seed were recorded. Komatsuda et al also teach preparation of mapping populations and preparations of DNA and clones with RFLP, screening oligonucleotides, analysis of molecular markers and linkage. Komatsuda et al further teach that the vrs1 locus controlling two and six-rowed spike in barley was mapped by backcross derived lines BC7F1 and BC6F2 plants and showed markers MWG801 (3.1 cM), cMWG699 (0.1 cM) and MWG865 (0.9 cM) are closely linked to the vrs1 locus (see the whole document, especially, pages 249, Methods and Materials; and Results).

Tanno et al teach identification of six-rowed cultivated barley using DNA marker cMWG699 that is closely linked to the vrs1 locus; DNA amplification and restriction analysis which showed three haplotypes in barley cultivars and analysis of their DNA sequence suggested that six-rowed barleys had differentiated from two rowed barleys, may be by mutation at vrs1 locus (see, Materials and Methods; and Results on pages 55-58). Tanno et al cites Komatsuda et al (1999) above.

Hence, the instantly claimed methods and barley plant/seed are indistinguishable

from the prior art barley plant/seed based on the teachings of the specification.

Alternatively, if the claimed methods and barley plant/seed are not identical to the prior art methods and barley plant/seed produced by said methods, then it appears that they differ from the prior art plant/seed due to routine optimization methods and of minor morphological variation in the plants/seed, wherein said minor morphological variation would be expected to occur upon cultivation of said plants on different soil types with different nutrient supplements and under different environmental growth conditions such as temperature, humidity, light, etc. in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to the prior art seed.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEDINA A. IBRAHIM whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH (8:30-5:30) and every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Grunberg Anne Marie can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
4/28/08

/Medina A Ibrahim/
Primary Examiner
Art Unit 1638